An Epidemiological Approach to the Correlation of Patient Safety, Deterrence, and Defensive Medicine

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Numerous studies point to links between patient safety and malpractice claims. Two predictions are prominent: (1) better patient safety leads to fewer medical errors and fewer malpractice claims, and (2) over-aggressive malpractice compensation encourages *defensive medicine*, where physicians attempt to reduce malpractice risk by ordering unnecessary medical procedures (or foregoing certain types of care). This study expands on this literature by introducing a unique measure of patient safety: the number of deaths due to medical complications. To compare this measure with paid claims, the study uses nationwide multiple mortality data collected by the National Center for Health Statistics (under the Centers for Disease Control) with data about paid malpractice claims from the National Practitioner Data Bank. Using hybrid fixed/random effect negative binomial models, this study investigates associations between paid malpractice claims alleging death, and deaths reported to the NCHS as occurring because of complications or accidents related to medical care (iatrogenic causes of death). The study finds (1) a positive association between deaths due to medical complications and subsequent paid malpractice claims; (2) a small, but positive association between paid malpractice claims and subsequent deaths due to medical complications; and (3) an increase in deaths due to medical complications in states that have experienced drastically large increases in malpractice claims for several years. These results are consistent with *both* proposed associations: from patent safety to malpractice claims; and from malpractice claims to patient safety. This suggests a mutually reinforcing endogenous system between malpractice claims and patient safety.

**Working Paper**

# Introduction

A number of studies have identified trends and changes in medical malpractice claims over time, including the waxing and waning of claims and responses to these changes. Much of the literature is focused on changes in law and policy designed to reduce the number of medical malpractice claims, or tort reform.[[2]](#footnote-23) The thrust for much of this research is to distinguish malpractice claims that result from misconduct and error from malpractice claims that are merely spurious.[[3]](#footnote-25) More recent work has built on this by specifying detailed cost-benefit analyses over across increasing numbers of medical procedures and increasingly refined measures of patient quality.[[4]](#footnote-26) Separating these claims is both a theoretical and empirical project. The fundamental issue is identifying the inter-relationship between malpractice claims and medical care. The particular pathways from medical care to malpractice claims focus on quality of care. The suggested association is that better medical care leads to fewer claims, and conversely that worse medical care leads to more claims.[[5]](#footnote-27) This association is the implicit design of malpractice law and policy: that the the frequency of malpractice claims depends on the quality of patient care. This is not the only directional association that has been proposed, however.

There are also assertions that the type and frequency of malpractice claims impacts the quality of patient care by leading physicians to practice defensive medicine.[[6]](#footnote-29) With defensive medicine, a physician’s treatment decisions are focused on minimizing the risk of malpractice claims instead of the maximizing patient outcomes. Research along these lines ordinarily focuses on physician practice, and often find increased health care costs from unnecessary tests and procedures.[[7]](#footnote-30) However, an even more troubling implication for defensive medicine is that an increase in unnecessary medical care should also lead to poorer patient health. Any health procedure has an inherent risk, and over-treatment should lead to larger numbers of detrimental outcomes, stemming directly from medical care.[[8]](#footnote-34) Thus, if defensive medicine results in suboptimal patient care, it should also be observable in population health, and not solely physician practice and health care costs. If these effects are observable in population health, as predicted, defensive medicine is also a population health issue.

This study addresses the population health issue directly and thereby makes two novel contributions: (1) analyzing the associations between patient safety and malpractice claims in *both* directions, and (2) bridging the legal studies literature with population health and social epidemiology. Taking its cue from research in population health, this study uses the multiple morbidity file collected from each state and aggregated by the National Center for Health Statistics under the auspices of the Centers for Disease Control (NCHS) for the years 1999-2008.[[9]](#footnote-36) Using this file, I identify trends for causes of death related to complications or “misadventures” of medical care. While this measure has not been used for quality of care in prior work on medical malpractice, it is similar to the adverse events measures used in prior studies focused on a smaller geographical areas and particular hospitals.[[10]](#footnote-38) It is also administrative data collected by the same government agency (and in a similar manner) as birth records that have been used to study defensive medicine related to births.[[11]](#footnote-39)

Expanding to this broader measure of mortality due to medical complications allows nationwide analysis instead of just a few states, or a few hospitals within states, but also looks at a broader swath of patients than those giving birth. I combine the NCHS data with data on paid malpractice claims from the National Practitioner Databank (NPDB) for the years 2003-2008.[[12]](#footnote-41) As discussed more fully below, to maintain the comparability of the claims and the mortality dataset, only serious malpractice claims, *i.e.* those alleging death are utilized.

These two datasets provide for parallel time series across states. Employing a hybrid negative binomial count model (which includes a state-level fixed effect and differenced component), I find (1) a positive association between the number of deaths due to medical complications and subsequent paid malpractice claims based on allegations of wrongful death; (2) an association between paid malpractice claims based on allegations for wrongful death and subsequent deaths due to medical complications, consistent with predictions of defensive medicine; and (3) a larger association between persistently rising paid malpractice claims in a state, and subsequent deaths due to medical complications. By finding an association in both directions between paid malpractice claims and measures of patient safety, this study suggests a mutually reinforcing, endogenous system between patient safety and the malpractice law and policy.

# Background

Fundamentally, law and policy surrounding medical malpractice relates directly to public health and safety. Medical practice is subject to both licensure and standard-of-care rules and regulations.[[13]](#footnote-43) These are intended to protect the public and protect the health and safety of the populace.[[14]](#footnote-45) In fact, some of the most basic medical practices, like washing hands, have made profound differences in patient outcomes, including reductions in mortality, although difficulties with compliance still exist.[[15]](#footnote-47) In addition, as with all tort law, medical malpractice is designed to take care of individuals wronged by the failure of the medical system to meet reasonably expected standards of care.[[16]](#footnote-50) Of course, these ideal designs are subject to the imperfections related to laws and agency externalities. One of the more concretely defined arguments against malpractice law and policy, is a fear that more aggressive malpractice systems can lead to defensive medicine.[[17]](#footnote-51) With defensive medicine, physician decisions are driven by a desire to avoid litigation and malpractice risk rather than an exclusive focus on patient safety and clinical considerations.

Studying defensive medicine has proven difficult for a number of reasons, including the breadth of medical systems and the heterogeneity in malpractice law across states. It is a well-known fact from social science that the breadth, importance, and jurisdiction of medical care and medical services have increased exponentially over the past century, a process known as “medicalization”[[18]](#footnote-52). At the same time, the various states of the United States have struggled with the appropriate level and manner of medical malpractice, introducing a great deal of variability in malpractice law and policy. Given the breadth and changes across medical care and malpractice context, most studies focus on some small piece of the puzzle, often slicing by geographical closeness or particular medical conditions, such as heart disease[[19]](#footnote-53) or hospitals within a certain states.[[20]](#footnote-54)

Similarly, this study focuses on a subset of malpractice claims. In particular, this study focuses on mortality and malpractice allegedly resulting in death. This provides three important benefits. First, cause-of-death statistics reported by each state have been aggregated and reported by the NCHS for decades. Combining this administrative data with the NPDB provides the opportunity to investigate the cross-influence for causes of death and malpractice claims. Second, the seriousness of the allegation–death–diminishes the the possibility that claims are foregone, because they are not worth litigating. In this way, this study can provide a nationwide representative analysis of the co-relation between malpractice claims and public health (as measured by mortality), but minimizes difficulties in making cross-state comparisons due to differential barriers to bringing malpractice claims across states. These differential barriers become more and more problematic the less serious the malpractice claim is, but this difficulty is minimized when considering the most serious injury, because pursuit of the claim is equally justified in all states. Third, and perhaps most importantly, the NPDB tracks only malpractice payments; it does not provide a baseline of similar medical events which do not result in malpractice claims. Because death, and cause of death, are carefully recorded by the NCHS, it is easy to produce a series of state-wide aggregate baselines for such events by combining the NPDB with multiple mortality file from the NCHS. Limiting the NPDB data to malpractice payments resulting in death allows cross-comparison relative to certain sorts of deaths, including those that did not lead to paid malpractice claims, establishing a comparison group.

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## Physician Decision-Making, Patient Safety, and Malpractice

Models of economic decision-making focus on the cost-benefit to a *physician* for either performing or avoiding a medical procedure. add some people to discuss here Frakes[[21]](#footnote-56) provides an important critique. He presents a cost/benefit curve, and a stylized equalibria conditional on the complication levels presented by the patients, but convincingly argues that this ignores broader contextual constraints on physician activity. Specifically, …

In other studies, these same institutional constraints on physician decision-making have been broadly verified across a number of dimenstions. ```

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## Public Health and Mortality Due to Medical Care

Collecting cause-of-death statistics is perhaps the longest and most comprehensive public health data project ever. Some historians point to the origins of cause-of-death reporting to the institution of coroners in the Articles of Eyre in 1194,[[22]](#footnote-58) while others prefer to anchor it in the creation of boards of health in 15th century Europe.[[23]](#footnote-60) These two origins express the dual nature of cause-of-death reporting in the contemporary United States. The former arose with coroners as agents of state surveillance over death, and continues today to assist the state in maintaining its monopoly of lethal violence,[[24]](#footnote-61) to collecting fines and taxes,[[25]](#footnote-62) and demarcating the beginning or end of legal obligations and rights, like inheritance or Social Security payments. The boards of health arose from the desire to address serious pandemics of medieval Europe, and modern statisticians and public health professionals still use reported death statistics to understand and eliminate public health hazards.[[26]](#footnote-64)

Historically, the basic categorization of death was dichotomous: deaths were either unnatural, resulting directly from human intervention, or deaths were natural, resulting from nonhuman means. At the advent of germ theory, the classification of medical cause of death, nosology, became an expertise in its own right. The systems of classification and standardization of clinical objects have been an international project since the late 19th century under the expertise of nosology and the auspices of the World Health Organization (WHO) and its International Classification of Disease (ICD) system. The United States has used the ICD since 1900,[[27]](#footnote-65) and has been at the forefront of initiatives in revising the ICD and the automated coding of death certificates to match the categories of the ICD.[[28]](#footnote-67) The ICD system consists of a preset list of acceptable clinical diagnoses causing or contributing to death, and a set of decision rules for selecting the underlying cause of death from among clinical diagnoses presented on any death certificate. The list and the coding rules, where implemented, provide comparability of death statistics across geographical space and over time.

The ICD provides a comprehensive classification system, forking dramatically from the simple division between natural and unnatural causes to include detailed clinical descriptions. The most recent version of the ICD utilized for coding cause of death, ICD-10, became effective in the United States beginning 1999.[[29]](#footnote-68) And the nosological classifications are extremely detailed and comprehensive. ICD-10 contains over 8,000 separate causes of death.[[30]](#footnote-70) These causes of death include things like 19 types of falls[[31]](#footnote-72) (W00-W19; distinguishing falls from ladders and falls from stairs). It also includes a number of causes of death directly relating to some problem in medical care, such as the “[f]ailure of sterile precautions during surgical operation” (Table S-1, Y62.0). Analyzing causes of death categorized under the ICD usually utilizes a clinically significant aggregation classification. The most common aggregation is the 113 clinically significant causes of death prepared and published by NCHS.[[32]](#footnote-73) Lists of these clinically significant aggregations are readily available and updated along with changes in the ICD. One of these clinically significant categories is “Complications of medical and surgical care.” A comprehensive list of these is cataloged in supplemental Table S-1.[[33]](#footnote-74)

Exactly how this category relates to quality of care and medical error is a subject of debate, with some analysts suggesting that it under-reports errors and others suggesting it over-reports errors. While these causes of death are not, strictly, related to medical errors or failures to follow the standard of care, they *are* causes of death that are specifically related to medical care. In other words, these causes of death indicate that some medical intervention was a direct (*i.e.* “but for”) cause of death for the individual in question. Some medical doctors analyzing medical errors in hospitals claim that these these causes of death far understate deaths resulting from preventable medical errors. With respect to causes of death, Makary and Daniel[[34]](#footnote-76) claim that medical error is the third leading cause of death in the U.S. They note that there is no specific way to identify cause of death relating to medical error under the ICD, and use a meta-analysis from studies to extrapolate the rate of errors causing deaths in hospitals, where error rates are known to be high.[[35]](#footnote-78) Similarly, other physicians involved in epidemiology suggest that adverse events (many of which are contained in Table S-1) are essentially preventable.[[36]](#footnote-82) From this perspective, causes of death due to medical complications are likely to represent an under-reporting of death due to medical error and malpractice. Despite the fact that the measure is imperfect, it is similar to adverse event reporting from hospitals, and does provide a measure of iatrogenic (arising from medical care) events, a predicted result of defensive medicine.[[37]](#footnote-84) Whether it provides a complete set of deaths related to error or not, it should rise and fall with increases or decreases in patient safety.

## Patient Safety and Paid Malpractice Claims Alleging Wrongful Death

*Quality of Patient Care.* Unlike empirical studies in public health and medicine which measure error rates and adverse events rates relative to the population, empirical studies of malpractice rates are often measured relative to physicians, and sometimes weighted by the amounts paid in medical malpractice. Most of these studies are concerned with explaining changes in these rates over time, and they advance a number of reasons to explain changes in the numbers of medical malpractice claims.[[38]](#footnote-86) Explanations for changes include the following: (1) tort reform, (2) health care quality, (3) rising litigation costs, (4) more hospital-employed physicians (hospitals pay instead of physicians, declining the amount of payments), (5) NPDB and settlement, (6) changes in personal injury claims in general.

The link to public health, and the focus of this study, is the inter-relation between health care quality (as measured by mortality by complications) and malpractice claims. Medical care does result in errors, but most errors do not lead to legal claims.[[39]](#footnote-87) However, the majority of legal claims do involve errors.[[40]](#footnote-88) Using a sample of claims from California, researchers associated with RAND have identified a strong negative correlation between increased patient safety indicators (PSI) (as reported by hospital adverse events) and decreased malpractice claims.[[41]](#footnote-90) A similar data strategy is employed by Black and Zabinski[[42]](#footnote-91) in Texas and Florida, making similar findings using hospital and county fixed effects regarding claim rates.

The basic relation here is that the quality of patient care is associated with subsequent malpractice claims. Better patient care is associated with subsequent drops in malpractice claims, while worse patient care leads to increases in malpractice claims. As outlined above, it is difficult measure the quality of patient care and a number of different avenues exist; however, relative changes in the number of deaths from medical complications provides a reasonable operations. Measuring the quality of patient care in terms of mortality from complications, this leads to the following hypothesis:

**Hypothesis 1:** Changes in counts for causes-of-death resulting from medical care (complication causes) are associated with subsequent changes in paid malpractice alleging wrongful death in the same direction.

*Defensive Medicine.* On the other side of the coin, changes in the number of paid malpractice claims should be associated with changes in future quality of patient care. In particular, rising medical malpractice claims (particularly when these are known to physicians) are predicted to lead to suboptimal patient care through defensive medicine.[[43]](#footnote-93) Instead of focusing solely on clinically appropriate treatment for the patient, doctors become increasingly concerned with minimizing malpractice risk. Accordingly, they over-treat by providing additional and unnecessary tests and procedures. While most defensive medicine studies are focused on costs of care, inappropriate over-treatment also carries with it risks (including death). As such, this sort of defensive medicine, if it occurs, should be observable in population health statistics, such as an increase in deaths due to complications of medical care. This leads to the following hypothesis.

**Hypothesis 2:** Increasing numbers of of malpractice claims are associated with subsequent increases in the number of deaths due to medical complications.

Finally, the association of increases in medical malpractice claims with defensive medicine relies on physician awareness of changes. Small perturbations in malpractice claims are unlikely to be noted by physicians. However, spikes in malpractice claims that are out of the ordinary, or significant changes to medical malpractice law are almost certain to be reported on and noted by medical providers. For this reason, the association between malpractice claims and complication deaths should exist (and more strongly) for spikes or significant changes in malpractice laws. This leads to the following, related hypotheses:

**Hypothesis 3a:** Spikes in malpractice claims are associated with subsequent increases in the number of deaths due to complications of medical care.

**Hypothesis 3b:** Tort reform changes are associated with subsequent increases in the number of deaths due to complications of medical care.

# Data and Methods

To test these hypotheses, this study utilizes two sets of publicly available administrative data reporting state level statistics. First is the multiple cause of death file from the NCHS (available from the public CDC Wonder database). This is an aggregation of all cause of death statistics throughout the United States. Whenever an individual dies in the United States—man, woman, or child—a coroner or medical examiner (depending on the context of death and the local laws) executes a death certificate and can identify up to 20 separate causes of death.[[44]](#footnote-95) The death certificate is collected by each state and delivered to the CDC. At the CDC, the death certificates are subject to a nosological analysis which translates the clinical identification from the death certificate into one of the 8,000 acceptable diagnoses, again, allowing up to 20 different causes of death. The CDC Wonder online database allows aggregation of these records by cause of death, including any of those deaths listing complications of medical care as a cause.[[45]](#footnote-97) A list of these causes of death is included in in the Appendix as Table S-1. The second dataset used for the study is the paid claims data from the NPDB public use data file.[[46]](#footnote-98) The NPDB collects national data on claims paid for medical malpractice, and, since 2004 includes the severity of the claim. This includes data from physicians (and occasionally other medical practitioners) who make payments due to a claim of medical malpractice.

These two files provide measures of cross-influence of malpractice claims related to mortality, and mortality directly related to complications of medical care. First, patient safety is operationalized as the number of deaths in a state due to *complications*, which is measured simply as the number deaths from complications of medical care in each state, each year. *Malpractice claims* are measured from the NPDB as the number of paid claims resulting from death (which amounts to approximately 1/3 of the paid claims in any given year). Because mortality and cause of death differ significantly between men and women, I distinguish between paid malpractice claims and deaths resulting from complications by gender, with *female* standing as a dummy indicator for women.

*Changes in Malpractice Context.* To adjust for the malpractice and tort reform context in each state, I include a dummy variable for each state and each year to indicate whether the state has a damage cap for malpractice claims, following Paik, et al..[[47]](#footnote-99) In addition, *malpractice spike* identifies whether there was a significant spike in paid malpractice claims for the state/gender combination. Specifically, it is a dummy variable indicating whether the change between the lagged malpractice value between the current year and the previous year is in the top 90th percentile of such changes.

*Testing the Cross-Influence of Paid Malpractice Claims and Patient Safety.* In order to appropriately test the cross-influence of malpractice claims and patient safety on one another, estimated models include a time-lagged component. The most straightforward approach is to demean or use a first-difference estimator in the relevant models. This works in a straightforward manner for the association of malpractice claims to subsequent causes of death (hypotheses 2 and 3), because paid claims occurring in a particular year are immediately observable as are deaths related to medical complications.

For testing the association of patient safety on malpractice claims, the issue is more complicated because there is a delay between the occurrence of the event (death) and observation of the paid malpractice claim. The delay has been calculated to average about four years for most claims.[[48]](#footnote-100) Simply put, there is some required period of time after death, but before the malpractice payment for each and every case, and while the mean is approximately four years, there is variation in lags between the event and payment. This means that each year of reporting for malpractice claims contains a mixture of years related to patient safety. Accordingly, failure to adjust for the time delay would reverse the direction of the association in time, testing the association of patient safety on malpractice claims for events occurring several years prior.

There are a number of possible ways to adjust for this delay, including limiting the dataset and imputing values for the malpractice claims. In this study, I take a combined approach. First, I exclude all years past 2008, to ensure there is a sufficient time-delay for most of the claims to result in final payment. Second, I calculate the mean of complication mortality for several years prior to the year in study (*lagged complication mortality*). To identify the appropriate years, I calculate actual time-lags from the NPDB. The NPDB provides information on the date of the last event (“malyear” in the codebook) as well as the date of malpractice payment. Calculating the difference between the last known malpractice event and malpractice payment identifies the length of the time delay.

Figure 1 and Table 1 below identify the distribution and cumulative proportion of claims related to the time delay as observed in the NPDB. As illustrated below, while the mean is 4.63 years, the bulk of paid claims for mortality occurrence happen between 2 and 5 years after the occurrence (approximately 64% of the sample). To correct for delayed observation of malpractice payments, models testing the influence of patient safety on paid malpractice claims (hypothesis 1 and 2) use the mean number of deaths related to complications from 2 to 5 years prior to year of the paid claims. This provides a smooth and sensible imputation for patient safety given the distributions pictured in Figure 1.

[Table 1 about here]

[Figure 1 about here]

*Time Series Analysis.* Exploiting the panel nature of the data, I estimate hybrid random/fixed effects negative binomial models, adjusting for state and gender-specific effects.[[49]](#footnote-101)

I utilize this approach rather than a state-level fixed-effects approach for two reasons. First, the dependent variable in all instances is a count variable, and the fully conditional “fixed effects” models do not control for all stable state-level characteristics.[[50]](#footnote-102) The hybrid model is both more efficient and less biased than the fully conditional “fixed effect” negative binomial models. Second, because the measures of patient safety and paid claims are measured grossly, I anticipate small effects, making efficiency of the method an important consideration.[[51]](#footnote-104)

Written as a two-level model, these take the following form:

Level 1 (within-state effects):

Level 2 (between-state effects):

Where is the count of paid malpractice claims or deaths due to medical complications (dependent on the model) in year for state . represents the negative binomial link function (log-linear) described more fully in Allison.[[52]](#footnote-105) is a matrix of time-varying characteristics for each state, including the lagged value of paid malpractice claims or medical complications (depending on the model) and whether the state has a currently imposed damages cap (as a measure of tort reform measures within the state). is a matrix of fixed state characteristics, including a dummy variable series indicator for the patient gender and year fixed effects (to adjust for the declining trend of paid claims). This hybrid model identifies the *within-state* effects () over time, which indicate the predicted effect of a change in the relevant variable on any state with respect to the predicted count of paid malpractice claims or deaths due to medical complications. It also identifies the *between-state* effects at level 2, including a vector of effects for constant state characteristics along with a constant (intercept) effect () and the between-state effects of time-varying variables (). The random errors of level two across states () are assumed to be distributed normally with mean 0 and variance .[[53]](#footnote-106) These models are estimated using Stata’s xtnbreg function. Notably, different modeling strategies, including a feasible generalized least squares estimator, within-state fixed effects estimators, and differing link functions (linear, Poisson) all return similar substantive results.

# Results

The descriptive statistics provide some preliminary evidence that there is a relationship between paid malpractice claims and deaths due to complications in each state. Table 2 provides basic descriptive statistics across the relevant years for both dependent variables, as well as the proportion of states with a damage cap. These figures are measured within each state, and separately for men and women. In each year, there is a decrease in the mean of both paid malpractice claims and deaths due to complications of medical care, which is consistent with a long-term decline in claims.[[54]](#footnote-108) In addition, there is a slight increase in states implementing a formal damages cap over this period.

[table 2 about here]

Figure 1 provides more detail regarding the dependent variables The left panel illustrates the distributions of both dependent variables. The box plots illustrate that both have long right tails. The wide variance given the relatively smaller means are suggestive of an overdispersed counting process. Visually, the distributions are quite similar, although deaths due to complications appear to be larger by a factor of about 10. Means for paid malpractice claims rest between the mid 20s and mid 30s (column 1 of Table 2), while the means for deaths due to medical complications range between the mid 200s and low 300s (column 3 of Table 2). This is also mirrored in the distributions. For example, the largest extremes in the count occur in 2003 and 2004 for both variables (left panel of Figure 2). The right panel of Figure 2 is simply a scatter plot illustrating the joint distribution of paid malpractice claims and deaths due to complications of medical care. The plot shows a fairly consistent and positive association between both variables, which appear to positively associated.

[figure 2 about here]

Table 3 reports results of a negative binomial hybrid regression with paid malpractice claims as the dependent variable. Table 3 provides support of hypothesis 1 showing an association between deaths due to medical complications and subsequent paid malpractice claims (based on claims of wrongful death). Model 1 provides a baseline without deaths due to complications. This model provides a number of inferences consistent with prior literature. For example, the year fixed effects all show an increasingly negative association, showing a year-over-year decline in paid malpractice claims.[[55]](#footnote-109) Model 1 also shows a negative effect for females, showing a smaller number of paid claims are based on allegations of harm to women. For damage caps, there is a negative, but insignificant effect in the between-state effect of damage caps (4th row of Model 1).[[56]](#footnote-110) This suggests that there are no differences between states that have long-term damage caps and states that do not have damage caps over the period. In contrast, the *within-state* effect of damage caps is significant and negative. This represents the effect of a state changing it’s damage-cap status. In other words, the adoption of a damage cap is associated with a decline in paid malpractice claims. This pattern is consistent with research suggesting that damage caps have primarily a short term impact.[[57]](#footnote-111)

[table 3 about here]

Model 2 includes the direct test of hypothesis 1 by including lagged number of deaths due to medical complications (*lagged complication mortality*). There is a significant and positive effect for *both* the within-state and between-state effects (rows 1 and 3 of Model 2 in Table 3), consistent with the predictions of hypothesis 1. Figure 3 plots predicted number of paid claims conditional an the number of deaths from complications (holding all other variables at their means).

[figure 3 about here]

Figure 3 shows a fairly small, but noticeable increase in paid malpractice claims as deaths due to medical complications increase, predicting an increase of approximately 25-30 paid claims for differences of 400 deaths due to medical complications between states. Within-state differences are even smaller, but provide even stronger evidence of the association, because it compares changes across the *same state* (with fixed state characteristics held constant). Mean changes of lagged complication mortality () is centered on 0, but an increase of 200 deaths due to medical complications within a state leads to an increase of paid claims of about 7. Which, while small, represents an increase of almost 25% from the mean counts of paid claims (*see* Table 1). Finally, in model 2, including lagged complication mortality mediates the negative association between women and paid claims, suggesting that there may be a gender differential in quality of care (and hence error and malpractice claims).

Table 4 tests the association between paid malpractice claims and subsequent complication mortality, or the defensive medicine hypotheses (hypotheses 2-3). Table 4 provides support for hypothesis 2 and 3a, that paid malpractice claims, and spikes in paid malpractice claims are associated with subsequent mortality from medical complications. However, there is no support for hypothesis 3b, that tort reform (measured by damage caps) has any association with subsequent mortality from medical complications.

[table 4 about here]

Table 4 presents the results of 3 nested models. Model 3 of Table 4 provides a baseline model similar to model 1 of Table 3, which also provides a test of hypothesis 3b. Model 1 shows no statistically significant association between damage caps and deaths due to complications of medical care, whether *between-state* or *within-state*. This model does, however, show a year-over-year decline in these deaths as shown by the negative coefficients for the year fixed effects. In addition, there negative coefficient for female indicating fewer deaths from complications are assigned to women on their death certificates.

Model 4 of Table 2 provides support of hypothesis 2 that increases in paid malpractice claims at both the *between-state* and *within-state* levels (rows 1 and 3). As with the association in hypothesis 1, this is a small, but statistically significant set of effects. The between-state effect is plotted in Figure 5 below.

[figure 5 about here]

Figure 5 shows that states with higher average levels of paid malpractice claims have, on average, higher numbers of deaths due to medical complications in subsequent years. There is a fairly steep increase, but the uncertainty in the estimate also increases dramatically after about 80 paid malpractice claims. In addition, there is a small, but statistically significant effect for *within-state* changes as shown in row 1 of Model 4. This means that states with increasing (or decreasing) numbers of paid malpractice claims have increasing (or decreasing) numbers of deaths due to medical complications in subsequent years.

Model 5 of Table 4 provides support of hypothesis 3a that large spikes in paid malpractice claims (defined as a year-over-year change in claims that is in the top 90th percentile of all observed changes in claims) is associated with subsequent increases in deaths due to medical complications. In this case, the *between-state* effect is positive and highly significant; whereas, the within-state effect is not. This means a single-year spike in malpractice claims is not statistically different from a smaller increase. However, the *between-state* effect measures the number of times a state experiences these spikes in malpractice claims. This coefficient shows that large increases in paid malpractice claims over more than one year is associated with larger numbers of deaths due to medical complications. States with 2 years of spikes in paid malpractice claims are predicted to have 104 (80-130, 95% C.I.) more deaths due to medical complications per year, and states with 3 years of spikes are predicted to have 203 (122-284, 95% C.E.) more deaths due to medical complications per year.

# Discussion and Conclusion

This study set out to investigate the association between paid malpractice claims alleging wrongful death and patient safety, measured by the mortality due to complications of medical care. From the negative binomial hybrid fixed/random effect models, there is evidence of a associations as predicted by the hypotheses. First, there are positive associations between deaths due to complications (indicative of poorer patient safety and harm from medical care) and subsequent Paid malpractice claims as predicted by hypothesis 1, summarized in Table 3, and illustrated in Figure 3. This association applies at both the between-state level and the within-state level. This means that states with more deaths due to complications, generally have more paid malpractice claims 2-5 years later. It also means that when the levels of complications rise within a state, that state generally has more paid malpractice claims 2-5 years later. Second, Table 4 shows evidence consistent with theories of defensive medicine. First, there is evidence (again both within- and between-state) that higher levels of paid malpractice claims are associated with subsequently higher numbers of deaths due to complications of medical care (hypothesis 2). These direct associations are relatively small; however, except for the case where a state consistently experiences large increases in paid claims for medical malpractice (hypothesis 3a). Finally, there is no evidence that tort reform has any direct effect on subsequent numbers of deaths due to the complications of medical care (hypothesis 3b).

As a whole, this study provides evidence of the expectations predicted in the literature. Patient safety and medical error are associated with medical malpractice claims. In addition, there is some evidence of the defensive medicine thesis; although, the association is generally small in magnitude paid malpractice claims are positively associated with subsequent levels of deaths due to complications of medical care (iatrogenic causes). Importantly, however, the defensive medicine effect with the largest magnitude appears to occur in states with repeatedly large increases in malpractice claims (as illustrated by the between-state effect of spikes in malpractice claims in Model 5 of Table 4). Ultimately, these associations suggest that patient safety and medical malpractice claims may be self-reinforcing processes, or processes that we should expect will rise and fall together. It also suggests that public health is harmed when there are sudden spikes in the number of paid malpractice claims. This issue is not only one for costs of medical care, but is observable in cause of death statistics and a public health issue.

A few limitations to the study are worth noting. First, it is limited to malpractice claims and medical events resulting in death. While studying these important claims has significant advantages—namely readily available data and nationwide coverage—it is not clear how cross-applicable these claims are to other types of medical malpractice claims. In addition, despite statewide coverage, the average numbers of deaths due to complications of medical care and paid claims resulting from death are relatively small. It is entirely possible that the bulk of these numbers are driven by small areas within states that are especially prone to poor medical care and/or more aggressive malpractice claims.

Despite these limitations, this study shows the usefulness of combining agency data, and approaching the malpractice and defensive medicine issue from a population health perspective. In addition to providing evidence of the dynamic relationship between malpractice claims and patient safety, this study’s focus on rates relative to patients and the population reveals interesting relationships that warrant further exploration. For example, rates of death due to complications as well as the number of paid malpractice claims are both lower among women than among men. Future work can explore these gender differences, as well as investigation particular causes of death (such as contrasting cancers and heart disease) and smaller-scale geographic areas.

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